THE ELECTROSPUN FABRICS AS A HEART VALVE LEAFS

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Introduction

The population at risk for heart disease especially aortic stenosis is increasing. The estimation of this risk is 80% of adult population in which may appear symptoms of aortic stenosis. The survival rate for patients who begin experiencing its symptoms is 50% at 2 years and 20 % at 5 years without aortic valve replacement.
There are two ways of intervention in this case: surgical (open chest) and less invasive transcatheter aortic valve implantation (TAVI) also called TAVR, transcatheter aortic valve replacement. The TAVI procedure is applied mostly for patient for whom an open heart procedure poses intermediate risk. For that reason patients in their 70s or 80s are better candidates for this type of surgery.
The TAVI procedure is surgical minimally invasive, repair the valve without removing the damaged valve. Instead of old valve the new is placed into the aortic valve's place.
The TAVI heart valve construction is based on metal stent with leafs attached which is before implantation crimped to the low dimeter on catheter balloon. The crimped form is entered through the femoral artery (large artery in the groin) which does not require a surgical incision in the chest or entering through a large artery in the chest or through the tip of the left ventricle (the apex), which is known as the transapical approach.
[1] Herein, it is described the results of mechanical test investigation on non-woven matts obtained *via* electrospinning and matts obtained *via* combined methods (electrospinning – electrospray). The tested fabrics were also easily assembled on stent. The preliminary result of mechanical test of formed heart valve leafs are presented.

Materials and Methods

The synthetic polymer for medical use was: Chronoflex Ar 22%(polyurethane-co-carbonate)(PU) manufactured by AdvanSource. The polymer was dissolved in DMAc to concentration 8% (electrospray purpose) and 18% (electrospinning purpose). The collector of electrospinning unit was modified for the valve leafs production and stent assembling occurring simultaneously. The parameters of electrospinning technique were optimized for electrospray film deposition and electrospinning fibers formation.
The mechanical test of material was determined using 4204 (Instron, Norwood, USA), crosshead section rate was 20 mm/min.
The mechanical test of heart valve leafs was determined using pump VDT-3600i(BDC Labs)

Results and Discussion

The electrospun fabric is characterized with lower value of stress and strain at the break in comparison to the film but fabrics may easily change its shape (not-merged fibers poses ability to move, presence of free volume-porous). Therefore more than 70% of multilayer fabrics thickness is built with fibers (see table combined sample). The rest (30%) of sample thickness is mix or film only. This mixed type of construction allows to seal the porous fibers material and prevent the blood seeps through the leafs.

TABLE 1. The results of mechanical tensile test of various form of samples

Lp.	samples (d=150μm)	Stress at the break [MPa]	Strain at the break [%]
1.	fibers	17.77±5.38	475.40±47.66
2.	film	27.38±3.71	884.25±15.20
3.	Combined (film and fibers)	32.47±2.24	745.80±44.26

Additionally, during stent crimping, attached material (combined fiber and film) stays in continues phase without any perforation. Macroscopic observation of heart valve after 60 days pump test (accelerated fatigue test simulation of 360 days heart valve work) revealed positive condition of all heart valve joint, although the material increased its dimension (stretched *ca.*10%). The stretch effect appeared during two starting days of fatigue test. Probably, fibers are being oriented under flow pressure in favorable shape.

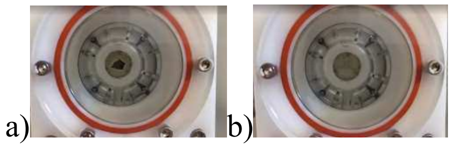

FIG. 1. Mechanical test of heart valve leafs: a) leafs position-open, b) leafs position-closed [2]

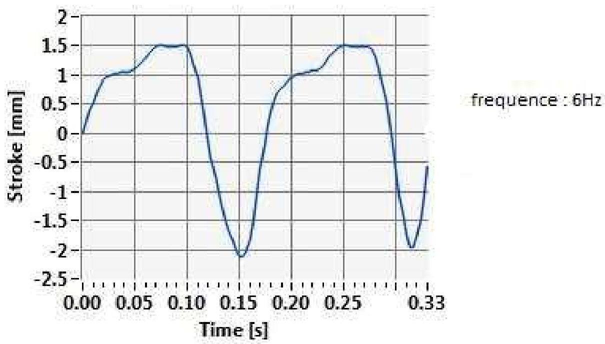

FIG. 2. The shape of wave during mechanical test of heart valve

Conclusions

The electrospun multilayer PU product is promising for the heart valve leafs forming. The mixed form can be easily attached to metal stent during electrospinning processing which decreases the time of the heart valve production significantly (lower end-cost). Nowadays, the sewing heart valve process takes more than 2 days of handcraft work. Additionally, the appearing deformation may help to obtain favorable shape of leafs.
Further work will be focused on production of valve possessing stable shape during fatigue tests.

Acknowledgments

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References

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[2] PN-EN ISO 5840-3 "Implanty sercowo naczyniowe protezy zastawki serca. Część 3: Substytuty zastawki serca implantowane technikami przezcewnikowymi"